IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION

RAMONA WINEBARGER and REX WINEBARGER,
Plaintiffs,

CASE NOS. 5:15CV57-RLV; 3:15CV211-RLV

v.
BOSTON SCIENTIFIC CORPORATION,
Defendant

MARTHA CARLSON,
Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION
Defendants

PLAINTIFFS OBJECTIONS AND COUNTER DESIGNATIONS TO DEFENDANT BOSTON SCIENTIFIC'S COUNTER DEPOSITION DESIGNATIONS OF ROGER GOLDBERG, MD TAKEN DECEMBER 13, 2013

BSC Counter Designation	Objection	Plaintiffs Counter Designation to BSC Counter Designation
rg121313, (Page 32:11 to 32:24) **32** **11 Q. Have you done work with something** **12 called the Pelvic Floor Institute?** **13 A. I have.** **14 Q. What have you done with the Pelvic** **15 Floor Institute?** **16 A. Well, the Pelvic Floor Institute** **17 was a program that was put together involving** **18 not only myself but a corps of academic** **19 clinicians and surgeons. And as a group we** **20 created, helped Boston Scientific to create** **21 what we felt were state-of-the-art teaching** **22 tools and academic teaching programs and** **23 syllabi. And through that structure we were** **24 involved with various training programs.**	**32:11-32:34 FRE 401, 402, 403**	
rg121313, (Page 328:3 to 328:24)	**328:3-328:23**	

328 **3 Q. Did you, for example, analyze for** **4 yourself the concept of pore size in the mesh** **5 that became the component part of the Uphold** **6 device?** **7 A. Well, you know, I consider myself** **8 somewhat lucky by timing that, you know, by** **9 the time my generation of surgeons entered the** **10 field the market was -- consisted solely of** **11 Type 1 polypropylene mesh products.** **12 So my expertise on mesh is** **13 certainly been consistently that I would only** **14 implant the Type I polypropylene mesh because** **15 of what we learned about nonType I materials.** **16 But that, again, preceded my time.** **17 As far as looking deeper again** **18 into the characteristics of polypropylene or** **19 the specific aspects of that mesh, no. But I** **20 had also, you know, done hundreds if not** **21 thousands of sling procedures. And like most** **22 of my counterparts had a great comfort with** **23 Type I polypropylene mesh as a very well** **24 tolerated material.**	**FRE 401, 402, 403, 701, 702**	
rg121313, (Pages 413:20 to 440:15) **413** **20 Q. State your name, please.** **21 A. Roger Goldberg.** **22 Q. Dr. Goldberg, tell the jury a** **23 little bit about you, your family.** **24 A. Well, I'm originally from Chicago** **414** **1 and I'm married. My wife is from the East** **2 Coast. We have four kids.** **3 I've done my training in various** **4 parts of the country. I spent about 10 years** **5 out on the East Coast doing my residency as** **6 well as undergraduate.** **7 We eventually found our way back** **8 here to Chicago where I did my fellowship** **9 training in urogynecology and was fortunate** **10 enough to be offered a position right out of** **11 fellowship.** **12 Q. Previously marked has been** **13 Deposition Exhibit Number 786.** **14 Does that reflect your** **15 education, training, and experience?** **16 A. It does.**	**BSC has previously designated this testimony. Plaintiffs adopt and incorporate any objections as set forth in their counter designations, if any.**	**Plaintiffs adopt and incorporate their counter designations, if any.**

Q. And tell the jury just briefly where you went to undergrad, medical school, residency, and then you have a Master's in Public Health too. Just describe those for me, if you would.
A. Sure. So, again, I grew up here in Chicago. I went out to Cornell University for four years of undergraduate. I was a

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pre-med student and an English major. Came back to Chicago for medical school at Northwestern University. And then actually took a year and did a Master's degree in public health at Johns Hopkins in Baltimore in epidemiology and biostatistics. And then subsequently went to Boston where I did a four-year residency in obstetrics and gynecology and then decided to go into this field, female pelvic medicine and reconstructive surgery, and wound up back here at Northwestern for that fellowship. That's a three-year training with both research and clinical and surgical training.
Q. So a fellowship would be something in addition to a residency?
A. A fellowship is above and beyond residency in obstetrics and gynecology.
Q. Where is your clinical practice here in the northern uppermost part of the suburbs of Chicago? Tell the jury a little bit about that.
A. So we're sitting here in Skokie, which is just north of Chicago, and I practice

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literally kitty-corner across the street. So in Skokie, Illinois. We are close to Northwestern University campus just to our east.
Our practice covers a geography which stretches north and west. So essentially the north part of Chicago. We service three different hospitals and have about four different office sites. I have four partners and we train three fellows.
Q. How many active patients do you have or patient charts do you have that are part of your clinical practice?
A. It's always hard to estimate. On

a busy clinical day, I'll see perhaps 30 patients. I operate on roughly four or five major cases per week. Sometimes more, sometimes less. But it's a very busy clinical practice. And multiplied out throughout the year, I'm sure that's several thousand active clinical charts at any time.

Q. So when we talk about urogynecology, explain to the jury what that is and give the jury some sense for how your

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practice may differ from a typical OB-GYN practice.

A. We're very, very highly focused. We're focused strictly on female incontinence and pelvic floor and sometimes pain issues. But largely prolapse and incontinence is enough to keep us busy on a day-to-day basis.

My average practice is really truly a blend of office and operating room, which is exactly what I love. It's a lot of variety.

Our treatment, our patient population because we're a referral center we often see quite a severe, a number of severe cases every day, patients that are referred from sometimes far away and largely servicing also women who live right here in the community, but with significant incontinence and prolapse symptoms coming for our help.

Q. Okay. So you've been practicing here in the North Shore medical group since what year?

A. Well, I was a fellow from 1999 through 2001, and in 2001 I was hired on. So

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my actual out of training practice began in 2001.

Q. Okay. And in 2013 you received a special distinction from your hospital group. Describe that for the jury.

A. Well, that was very recent. It was very nice. We've been privileged to receive a number of research awards and clinical awards, but this was special because it was from my peers. And I'll have to actually look to remind myself exactly what they call it.

But it was a very surprising award that I received called the Distinguished

Physician Award for our whole healthcare system. So that was a bit of a ceremony a couple of weeks back. Total surprise. **Q. Okay. You also serve on a professional society and you're on the board of directors for AUGS?** **A. That's right.** **Q. Describe what that is and why is that significant.** **A. Well, AUGS is our premier** **419** **organization. It strives to be the leader in female pelvic medicine. It's such an area of need. We've driven a lot of the research and discussion and awareness and science.** **I was asked to run for the board by the president at the time, Matt Barber, and I really had never thought about doing so. I had run committees for AUGS. And then ended up winning the board election, which has turned out to be a very interesting, engaged, and, you know, fun process to be a part of and certainly with lots of close colleagues that I've gotten to know better.** **Q. Okay. When you talk about your area of specialty -- and the jury may be familiar with stress urinary incontinence and pelvic organ prolapse -- I want to focus on the pelvic organ prolapse part of that.** **Describe why that's of interest to you and give the jury some sense for what that condition is and how it affects their lives.** **A. Well, prolapse and incontinence, they sound like small problems until you** **420** **have them. They are, in fact, first of all, highly prevalent. We find that in some way, shape, or form roughly 50 percent of women who have had babies, by age 40 even, can describe some loss of control over the bladder. Not to say they all need surgery. That's a different subject. However, this is a prevalent set of conditions that affects women sometimes at a shockingly young age.** **Women tend to retreat from often times a normal quality of life, give up exercise, not feel comfortable socializing. If**		

any one of us, you know, had a bladder accident right now, I mean you'd really have to stop and think if it were me, you know, what a fundamental loss of control and self-esteem that is. And it really truly every day is amazing to see how impacted these women are by prolapse and incontinence. And on the flipside it's truly a privilege to help to greatly improve their quality of life in really the most fundamental way.

Q. What about prolapse? What is prolapse and how can that affect activities of

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daily living?

A. Well, prolapse is essentially a loss of support involving the vagina or uterus. These are support defects, as we call them, that come in a variety, a whole range of severities.

So women with mild prolapse may not need any treatment. It might be something their doctor notices.

Women with severe prolapse are the ones that typically reach our office, feel like their insides are hanging out. I mean it's a very abnormal, uncomfortable feeling.

And to an extreme then when those prolapses start to progress, which they often do, that can really very significantly impact a women's comfort, again, exercising, walking, having sexual relations. That's the nature of prolapse.

Q. Okay. Let's focus, big picture. From the time of your fellowship to the time it ended, 2001, 2002, describe for the jury, just focusing on pelvic organ prolapse, describe for the jury what the treatment

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options were, okay, and then let's talk a little bit how these treatment options have evolved in the last 10 years.

A. Well, when I was a -- I've sort of been obviously witness on a part of the transition. We really have options and a toolbox now that didn't exist 10 or 15 years ago.

When I was a fellow, I caught the tail end of the era where we really had a fairly limited number of options.

In particular, women with prolapse, number one, they'd almost always get a hysterectomy. That was nearly a guarantee, which is a big deal. You know, it's individual to a patient how she feels about it, but many, many people feared pelvic prolapse repairs because they didn't want a hysterectomy.

And, number two, the treatment particularly of the cystocele. The so-called dropped bladder was described for generations of surgeons as the great challenge in pelvic support just because of the way the physics in the female body bear down on that area. And I

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as a fellow would routinely see women who considered us essentially a failure because we would perform a repair and they would come back, you know, a year later or less with some sort of bulge.

Q. You talk about repairs in this time period, 2001, 2002, what were the types of repairs that were initially attempted?

A. Well, native tissue repair, which I still do regularly, you know, but everything's individualized in this field, but native tissue repair was sort of the only option.

So when you talk about very specifically what areas have improved so much, when you look at the advanced cystocele, the dropped bladder -- native tissue repair for a dropped bladder is called an anterior repair or an anterior colporrhaphy. And that had a notably high rate of recurrence. There are other areas of prolapse that can recur but that was really kind of the focal point, an area that you could suspect might come back to re-prolapse down the road.

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And we had it, you know, a lot

of women viewed these repairs as well, they'll work for a few years and then you got to come back. And there was some fairness to that criticism, it was somewhat true.

Q. So how did your treatment practice then evolve to a point when you began to use additional tools like the term Capio? And give the jury some sense for what a Capio is and why that was, in your mind, an innovation that was useful in the treatment of pelvic organ prolapse.

A. Well, so Capio was a device that I actually had seen in my residency.

First and foremost, what Capio allowed us to do was a much, much smaller dissection, much less trauma to the tissues, to do what we call a sacrospinous suspension, which is a core procedure. For any urogynecologist like myself, to do a vaginal suspension many of us rely on the sacrospinous.

In the old days we used to have to use retractors. And it would actually be kind of a long operation, tough visualization,

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we'd use large deep retractors to expose the ligament visually.

So with Capio, and we were a part of this to help, you know, sort of push the best technique along with the Capio, we started to develop techniques that involved very, very small dissection, placement of the stitches without the retractors. And that translated into a quicker operation, less blood loss, just a much more elegant repair.

So for this so-called sacrospinous suspension, it was this gem of a device.

Q. And you have a Capio there. Why don't you show that for the video camera.

A. So this is the Capio device. And if you've never seen, obviously it might not make much sense, but it's actually quite simple.

The goal here is instead of, again, using a standard stitch technique deep in the body, we'd have to use long suturing instruments. Here, we can slide the device up, place it against the ligament -- and obviously

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I don't have this loaded with a suture. But it's a single press. And if you look carefully, I don't know if you can see it against my hand, there's a catch mechanism.

Q. Okay.

A. And so it basically places a suture with a very controlled depth. It'll never go deeper than this. We developed, again, a technique that was real quick and efficient for sacrospinous.

Q. Okay. So how did you use the Capio initially with something called biologic and then how did you evolve into polyform mesh and then evolve into the idea of the Uphold? Explain that for the jury's benefit.

A. Yes, so that's exactly right. So we had developed, around 2000, we published on this actually, the anterior approach to the sacrospinous, using the Capio was sort of a watershed transition.

Without getting too technical, this was apparently a much improved approach to the sacrospinous ligament deep in the pelvic area resulting in a better anatomic outcome

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than what had been taught in the textbook for many decades.

So on the heels of that, to answer your question, we then started to ask ourselves well, we have this really elegant fixation method, how can we start to tackle the cystocele. We keep seeing these cystoceles come back.

Q. And cystocele is the bladder?

A. That's the dropping of that anterior vaginal wall which provides a platform of support for the bladder.

So a woman will see a balloon of tissue coming out --

Q. Coming out of the vagina?

A. Coming out. And what she's seeing is actually the vaginal skin. But right behind that is the actual organ of the bladder. You don't see the bladder, but you're seeing the vaginal wall collapse underneath it.

So to elevate it in a way that would actually hold up durably in a reliable fashion, we started to ask can we begin to use 428 this technique not only to suspend the top of the vagina to the sacrospinous but can we incorporate something to reinforce the cystocele. And that, to answer your question, is where we got into the incorporation of biological grafts. Q. And what's a biological graft? A. So a biological graft, similar to how you have a skin graft put on a defect in the skin, these are biological products. They either come from human tissue or animal tissue. Q. Okay. A. In some cases they're actually autologous where they're harvested from the patient's own skin. I've never done that technique. But I for several years used an off-the-shelf product called Repliform -- Q. Okay. A. -- which was just a very, very well tolerated, been used for years in various degrees, various areas of surgery, had an excellent tolerability profile. 429 We actually incorporated Repliform into a Capio-based technique that started to move the needle fairly dramatically actually. Our cystocele recurrence rates which at our center had historically been around 42 percent actually started to decline by I think around 68 percent, drop in failures. Q. Okay. A. So that was very encouraging. And we started to in a sense gain a reputation for having, you know, developed this anterior apical new method. Q. Okay. And then you transitioned to using a mesh. Explain that to the jury. A. Well, so as the, you know, as the -- as mesh was becoming part of the discussion in surgery, you know, we started to ask ourselves, you know, the outcomes would certainly indicate that mesh can provide certainly a better anterior outcome. And even		

to this day, there's really uniformity that the randomized trials have shown that in terms of sheer anterior compartment support, you can get a phenomenally strong repair. We started 430 to ask can we incorporate a very simplified approach, you know, again, building on what we had done with Capio, leveraging what we had learned with Repliform and the biological graft, can we use the unique properties of mesh to actually reduce our fixation points. Because of the inherent bonding properties of mesh, you know, we could potentially do a lot less fixation, perhaps have less pain for the patient, and a quicker, simpler operation, which, you know, years later did eventually come to fruition. Q. How did you go from that intermediary step then to the device that the jury may be hearing about called the Uphold? A. So Uphold was -- so we were in our center, again, evolving from biological grafts to a mesh that we were cutting ourselves and having to stitch in. Q. Okay. A. And the sutures themselves tend to, with any surgery, cause pain, and also involve a lot of adjustment, fine-tuning, which is difficult, it's difficult to teach 431 and it's difficult to do. So Uphold was a true merge. And perhaps there was a lucky timing involved. But the technology that was being introduced to Boston Scientific's line called the mesh leg or the mesh arm which was incorporated into the Capio needle -- and Dr. Miller had contributed this technology -- came at the perfect time for all of us to realize, you know, boy, we can eliminate the suture tie-downs, we can make this operation even simpler. And so it was a collaboration of these two ideas into one. Q. So if you assume and assume with me that the Uphold would have received		

clearance from the FDA in late 2008, was there
a time prior to that where you were having your own clinical experience with a device that essentially was the equivalent of the Uphold? And describe that for me.
A. Well, yes, I mean and to varying degrees. And in the end actually, pre Uphold, we had experience with cutting down the Pinnacle device to the specs that we felt were going to be Uphold.

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Moving from that point in time actually a little bit further back, we had been cutting polyform mesh to sort of convince ourselves what's the best configuration here. So there was a period of time where we were self-shaping polyform and Pinnacle mesh to match the specs of what eventually became Uphold.
Q. And you have with you I believe an example of the Uphold. If you could hold that up.
So just describe what the various components of that are.
A. So I should have loaded this a minute ago because I'll show you right now. Let me show first the implant.
The actual implant is what you see here, the blue. It's very small. So this is the implant size. It has a top edge which fixes onto the top of the cystocele.
This little curvature on the bottom actually is designed to secure either onto the cervix, to fix onto the cervix, which would go right there, or to the apex of the

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vagina if a woman has had a hysterectomy before. These arms actually are what fixes the mesh into place. And to show you this, let me just load it up.
It's very simple engineering which I think is always, my feeling is simple is always good when it comes to surgery.
So the Capio needle loads into the device. It just pulls back into place. So the needle is now set in the device.
Q. Okay.
A. And I don't know if it'll go through a napkin -- I've never tried this as a

demonstration but it probably will. So if that's the ligament, say deep into the body, you place a suture -- this is an ordinary suture, no bigger than any other suture caliber we've used for years with Capio.

This is called a dilator tube. All the dilator tube does is as it passes through this ligament tissue creates just enough wiggle room, just that extra millimeter or two, to allow for passage of this component.

And this is a sleeve which you

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will see in a moment this is all going to be removed. The only implant left behind is the mesh. Just to show you how it goes through the ligament, it'll pull through. Obviously this is a napkin, so it's a bit challenging.

Whereas normally in years past we would have had to suture this down, this mesh will now self-affix into place. Now, it doesn't pass through and through the muscle. It's actually just making sort of a hairpin turn in a very, very defined small space.

Q. And what about the rest of the arm there, what happens to that?

A. This all comes off. I could do that if we had a pair of scissors or something to cut with.

Q. That's okay. I think we want to keep that intact, if we can.

A. Essentially this plastic, everything is removed except -- with the exception of the implant, which this implant will not only suspend the cervix or top of the vagina but also this main body of the implant sits underneath the cystocele. And the

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combination of the --

Q. The cystocele meaning the bladder?

A. The dropped bladder, the dropped vaginal wall.

Q. Okay.

A. This provides that reinforcement to that critical area which was at the highest rate of recurrence. And this implant unchanged from its original design has reduced our risk of cystocele recurrence literally by

about 95 percent.
So the number of women who have recurred after this to date with very careful follow-up, we always say we never know what's going to happen tomorrow, but it's truly changed the reality for these cystocele outcomes.
Q. Okay. How does the size of the Uphold compare to earlier generations of the transvaginal mesh products for pelvic organ prolapse? And you brought some.
A. I did.
Q. And let me, for the jury's benefit, let me mark as Exhibit 827 the Uphold

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and let me mark as 828 the Capio. And we'll have to figure out a more elegant way of preserving those.
(Deposition Exhibit Number 827 and Exhibit Number 828 were marked for identification.)
BY MR. KEENAN:
Q. What did you bring here and hold it up to the jury?
A. So this is a Prolift. Full disclosure, I've never used the device. This is something that I was able to get through training.
Q. Who makes the Prolift? Not Boston Scientific?
A. No. This is Ethicon. So this was one of the quote unquote first generation lift kits that came onto the market using a trocar system.
So the Prolift -- I would be unable to give a great demonstration of how this goes in. But I can show you the basic elements are, you know, just fundamentally different, which it does not take a pelvic

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surgeon to see.
So going back to the Uphold implant, this is it. I mean I have a small hand, it's in the palm of my hand, and this is the total Prolift mesh. This is just what it is.
There are anterior and posterior components. There are, as you can see, arms

that are designed to go through the gluteus muscles, the levator muscles, and the obturator muscles. And by "going through," what I mean is unlike the Capio where these arms of mesh just pass into the tissue a small degree and hitch on, these are arms that were actually designed to go from inside the vagina out to literally the external skin. How do we do that? Well, the technique was using a long needle, and this is what we call a trocar-based kit where basically this needle, believe it or not, would pass from an external incision, like near the buttocks, and the doctor would then fish this needle out through the vagina. Albeit certainly was used 438 successfully by a lot of good doctors out there, this you can see is just a very, very different mesh size and delivery system. These are the tubes that are used for the device just to facilitate the mesh placement. Q. Okay. Why don't you put that -- we'll collectively mark that as Exhibit 829. (Deposition Exhibit Number 829 was marked for identification.) MR. KEENAN: Why don't you put that back in the box. BY MR. KEENAN: Q. And then you brought another device made by another company. Just describe briefly what that is. A. Sure. This is Bard. And, again, I've never used this, so I can't give you an intimate introduction to it. But this is more of an isolated anterior compartment repair that Bard was -- Q. What's the name of this device? A. This is Avaulta. So this is Avaulta. It was designed as a four-arm 439 system, you know, with these arms going into the side wall muscles. So a through and through passage with needles. Similar in delivery system		

concept to the Prolift but obviously a somewhat scaled-down implant for single compartment use. Q. But also using the trocars as distinct from the Capio? A. Exactly. So the trocar -- just to show -- this is just a different shape. This is, again this is designed for passage from the external skin into the vagina. So inherently a different concept than a direct suturing technique using the Capio device. Q. Okay, okay. MR. KEENAN: Let's mark that collectively Exhibit 830. (Deposition Exhibit Number 830 was marked for identification.) BY MR. KEENAN: Q. And I think the jury understands this, but just so we're clear, you have no clinical experience with either of those two 440 trocar-based delivery systems. A. That's right. I literally never used one of them. Q. And why is that? A. I guess it's a funny way of putting it, but I grew up on the Capio. Again, I happened to train in the Capio fixation methods and actually early on started to innovate simpler ways of using the Capio. So by the time the trocar products entered the market, it was not even an afterthought to begin passing needles from outside to in. We knew very efficient ways of getting suture graft or mesh into place with a simple vaginal incision.		
rg121313, (Pages 442:14 to 444:21) 442 Q. Okay, okay. One of the things I want to -- going back to the Uphold, I wanted to direct your attention to an exhibit that is described as a technique spotlight. This is Exhibit Number 831. (Deposition Exhibit Number 831 was marked for identification.) BY MR. KEENAN: Q. It's captioned "A New 'Minimal	BSC has previously designated this testimony. Plaintiffs adopt and incorporate any objections as set forth in their	Plaintiffs adopt and incorporate their counter designations, if any.

23 Mesh' Approach to Apical & Anterior Prolapse." 24 (Document tendered to the witness.) 443 1 Just identify that for me, if 2 you would. And let's just take a minute to 3 identify what -- this is something you 4 authored; is that right? 5 A. That's right. 6 Q. Okay. And what is this? Let's 7 talk generally about what this is. 8 A. Well, this is a piece that is just 9 designed to basically give an overview. It 10 obviously was produced on the BSC end. It's 11 not meant to be an academic document but just 12 to give a fair overview of what the concept 13 here is, the principles that led to this 14 device, and also the experience that we had 15 had at our center, and also giving some 16 background into some of the literature. 17 Q. Okay. I think this has been 18 covered a little bit with plaintiffs' counsel. 19 But directing your attention to the second 20 paragraph of the first page inside, the 21 question was asked "What was the least amount 22 of material we could implant using the least 23 invasive means of fixation to achieve the best 24 results?" 444 1 Do you see that? 2 A. Yes. 3 Q. Describe how the Uphold 4 accomplished those goals. 5 A. Well, you know, the least amount 6 of material was -- this was a shockingly small 7 implant to a lot of people. But through our 8 device -- through that progression of device 9 development, we were fairly confident that 10 this was, you know, that this relatively small 11 implant would provide a Level I, II support. 12 The best means of fixation is 13 fairly self-evident from what I was just 14 showing you. The use of trocars was not in 15 question here. We needed something 16 Capio-based, no external incisions, and, more 17 importantly, no passing through sensitive 18 muscle groups of the body, and then achieving	counter designations, if any.	

the best results. I mean we were committed to following these patients, and we still are to this day.		
rg121313, (Pages 445:9 to 452:14) 445 Q. On the next page you talk about the no overlapping suture line. And I'll just read it here. "Thus far in our experience, it appears the rate of vaginal mesh erosion associated with our repairs is favorable as there is no overlapping of the mesh implant and the suture line." Do you see that? A. Yes, I do. Q. Explain to the jury how that was built into the design of the Uphold. A. Well, frankly this was about I think 30 cases into our Uphold experience. And I remember the day that we were operating, we realized gosh, why are we making a vertical incision, why not, you know, as with other 446 vaginal procedures we do, why not configure that incision to avoid overlap with the mesh. Q. And when you say "overlap with the mesh," just explain what you mean. A. Well, so at the end of the -- this would be a very crude rendering -- but if you look at the Uphold as an implant, I'll show it alone here, this is something we drew before for a different reason. But at the end of the day you either have to make an incision in the vagina that is closed in a configuration that's directly overlying the mesh, which we had done initially with very good success, we didn't have many exposures at all. But it was the sort of "aha" moment where why don't we just put our incision a few millimeters going this way above the mesh, so when we close it your stitch line, when you see that sutured vaginal incision nice and closed, would have no communication with the mesh, and over the mesh would just be intact vagina that was brought back up into place.	BSC has previously designated this testimony. Plaintiffs adopt and incorporate any objections as set forth in their counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

So it was just another principle

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that we felt might help to reduce mesh exposure and complications. And we still do it to this day. I like the technique.

Q. How have your patients responded to the Uphold? Just give the jury some sense for what your clinical experience has been with your patients using the Uphold all these years.

A. You know, it's been a real positive practice shift in many fundamental ways.

I just did two procedures yesterday. I wouldn't be doing the procedure if I didn't believe in it after all this time.

But these are patients who have in many, many cases been able to avoid a hysterectomy they didn't want. These are patients who we have been able to drive down the rate of cystocele or large prolapse recurrence from a 42 percent range to literally now we're looking at about 1 to 3 percent, which is a phenomenal reduction.

So for these women who I see every day who when I lay all options on the

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table with a vast amount of discussion these days, these women are going to the gym, they're traveling, they want to be lifting suitcases and squatting and exercising in the years to come and they in many cases don't want a hysterectomy. This turns out to be an excellent match for many of them.

And in terms of patient satisfaction, it's been tremendously positive. To date, I'll knock wood as I say it, I have never had to remove one of these implants. I've never seen an infection. I tell patients I've never seen a rejection certainly, I've never even heard of that. And this is I think one of the happier groups in my practice.

Q. Well, let's talk about, let's shift to talk a little bit about the published clinical studies of your device, the Uphold,

and I'm talking about both things published in peer-reviewed journals and also poster presentations.

I'm going to mark as Exhibit Number 832 a document that's entitled "Uphold Clinical Overview."

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(Deposition Exhibit Number 832 was marked for identification.)

BY MR. KEENAN:

Q. If you could describe for the jury what that summary exhibit represents.

(Document tendered to the witness.)

A. So this looks like it goes beyond the scope of just our practice, but several of these studies on here are from our division.

It looks like this is a compilation of not only the peer-reviewed publications but also some clinical posters presented at meetings.

You know, what this I guess I'll say overall because I've looked at this set of studies before, one thing that stands out is it shows a great consistency in terms of the safety.

Mesh exposure is not the only important issue to talk about in terms of safety, we need to talk about pain and dyspareunia. But if you look at the mesh exposure rate, it's very low, single digits for all of these studies, and low single digits at

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our institution and elsewhere with the De Tayrac study.

Our Vu et al. study, that's Andy Vu, he's the physician that drove the analysis of this International Urogynecology Journal study in 2012. This is important for me because it represents a snapshot of every Uphold case we had ever done.

That was the goal is to get every patient in. We literally mailed out Starbucks cards until we got a nearly uniform follow-up.

These were just very satisfied patients. The mesh exposure rate at that time was 2.6 percent. With re-analysis, that may

even go down. And very satisfied patients with excellent anatomic outcomes. So we continue to follow not only that cohort but the others very closely.

What's helpful with this compilation though is it shows me also in other people's hands, in surgeons' hands, and in other parts of the world, they seem to be getting a consistent result.

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There's absolutely nothing we do that is free of risk, but this shows me it's a very reasonable risk profile for a good anatomic outcome.

Q. Let's just pause for a moment and let's identify what studies then would not be reflected on this sheet, either because they are not finished or they're just beginning. So what additional studies a year from now may we have additional information about that would not be reflected in this exhibit?

A. Uphold is kind of in a unique position worldwide right now, and I think it's a great compliment to the device itself, is that it's being studied in many different arenas.

At our center, for example, there's a multi-center study that actually doesn't involve me but my senior partner, Dr. Sand, along with Dr. Culligan and Dr. Rosenblatt at Harvard, they have a multi-center study of Uphold.

There's an NIH-funded study. Essentially it's one of the pelvic floor

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networks. Two major studies actually. One looking at Uphold as a comparison to a hysterectomy. Another looking at Uphold in comparison to abdominal sacral colpopexy which is another very common procedure for advanced prolapse.

These are very prominent investigators, very high level studies, Level I evidence, very exciting to see it held up to

that level of scientific scrutiny. And then additional studies I should say in Australia and Europe. I have no connection to those, but it's nice to see that they're ongoing.		
rg121313, (Pages 453:9 to 459:13) 453 Q. Let me shift gears and talk a little bit about compensation, okay. There's been questions asked of you about how much money you've earned. Generally speaking, do you feel like you've been compensated fairly or unfairly? What would you say about the kind of money you've earned over this period of time? A. You know, I guess I don't look at things quite that way. I mean it is what it is. The work I've put into this is the equivalent of a whole other job. So I think that I've brought innovation to the field that I feel very, very proud of. If I had any doubt about that, I may have questions about making money outside 454 of my day job. But these I think are real advances in our field, and I see these advances helping women in real life. I see these women come back. So I'm comfortable with the fact that I made a business arrangement with Boston Scientific, and that this what I consider to be good work that I'm very proud of, and through a lot of hard work, has translated into that money. Q. Okay. I want to talk a little bit about training. Have you been involved in helping train physicians in the surgical techniques of implantation of the Uphold? A. Yes. Q. I want to hand you the Directions for Use, and I want to mark it as Exhibit 833. (Deposition Exhibit Number 833 was marked for identification.) BY MR. KEENAN: Q. Do the Directions for Use tell	BSC has previously designated this testimony. Plaintiffs adopt and incorporate any objections as set forth in their counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

physicians they need to get trained?
(Document tendered to the witness.)

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A. Yes.
Q. Exhibit 833 -- let me just to expedite things. The Directions for Use state that "Training on the use of the Uphold Vaginal Support System is recommended and available. Contact your company's sales representative to arrange for this training. Physicians should have experience in the management of complications resulting from procedures using surgical mesh."
You'd agree with that?
A. Correct.
Q. Okay. Give the jury some sense for what kind of training you have provided physicians in the field with respect to your device, the Uphold?
A. Speaking to my involvement?
Q. Yes.
A. Well, specific to Uphold, the training I've provided and my involvement with the Pelvic Floor Institute, which was a program that involved not only myself but other academic and nonacademic surgeons teaching cadaver labs, providing anatomy

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lectures and didactics.
I've also precepted doctors visiting my operating room just to look at our best practices. That's usually a fine-tuning issue, not so much for a new surgeon but somebody looking just to see the finer points of how we manage our operating room.
But largely through the Pelvic Floor Institute and through weekend cadaver labs.
Q. I'm going to mark as Exhibit 834 a document that I believe is from the Pelvic Floor Institute.
(Deposition Exhibit Number 834 was marked for identification.)
BY MR. KEENAN:
Q. Can you identify this for me?
(Document tendered to the witness.)
A. This looks like one of the slide decks that would have been used for the didactic portion of the Pelvic Floor Institute lab.

Q. There's a Table of Contents, Didactic Topics, on Page 2. Do you see that? 457 A. Yes. Q. What does this represent? A. This just represents an overview when doctors are arriving early in the morning to show them the topics that we'll be covering for that day. Q. And how long typically would the didactic go on for? A. Several hours. This was usually, my recollection, boy, probably a two- to three-hour chunk of time, depending on the number of questions and discussion. Q. There's a page here, I don't believe they're numbered, but there's a page here that has an illustration of the sacrospinous ligament. A. Okay. Q. What is that? A. Well, that's showing obviously kind of in a stripped down view of the -- it's showing a key element of the repair which is the surgeon's finger here identifying what's called the ischial spine, which is a little bit of a bony landmark. And then the Capio 458 being placed adjacent to that finger. It's actually in surgical terms quite a simple technique, but this is showing the relationship between the bony anatomy and the proper placement of the suture. Q. What about managing complications, was that something that was typically addressed in the didactic? A. Typically, yes. I mean naturally, and that became obviously a bit more detailed at certain points in time. But the management of surgical complications I think even in this slide deck is going to show up at the end. So this was a typical sort of set of slides. Usually we covered this as its own unit. Q. Okay. A. Oftentimes after the actual hands-on lab, we'd go and purposefully do this		

over lunch so that we had time to kind of dwell on questions, finer points, how do you manage this, how do you manage that, do you use estrogen cream, things along those lines. That's where the complications were usually covered. 459 Q. And after every one of these didactics and cadaver labs, did Boston Scientific endeavor to reach out to those who attended and evaluate whether they thought the training was useful and beneficial? A. I'm assuming that was every time. I know that they would often send us e-mails just echoing positive feedback. You know, a certain percentage of patients expressing that they love the course or would recommend it to their colleagues, whatever it may be. (Deposition Exhibit Number 835 was marked for identification.)		
rg121313, (Pages 460:7 to 462:11) 460 (Deposition Exhibit Number 836 and Number 837 were marked for identification.) BY MR. KEENAN: Q. And I've marked as Exhibit 835, 836, and 837. (Documents tendered to the witness.) Are these examples of the results of the feedback that we received back from those that attended? And are you copied on these? A. I recall being copied on several of these, you know. It seemed to me that for the vast majority of labs they'd collect this feedback. We sort of knew doctors were getting a great experience. They'd often tell us during the labs. But it was always nice to 461 see the formal feedback in the collection of this data. Q. And based on the evaluations received from those that attended, it looks like what, the rankings were -- A. Well, for the ones that you provided, I mean it looks like close to the	BSC has previously designated this testimony. Plaintiffs adopt and incorporate any objections as set forth in their counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

exceptional range, which is a good thing, in terms of the faculty, didactic, hands-on. And not to toot our own horns, because it wasn't just me, but I was never surprised by these results because it really was a very high caliber teaching module that was put together for really surgeons that came in oftentimes with a whole set of different interests and needs that day, but I felt like we could meet their needs very well. They invested a lot in the hemi-pelvis. It was a unique training environment. So I was never surprised to see the good feedback. Q. Okay. I want to shift gears and talk a little bit about what your clinical experience has been with respect to your 462 clinical observations with respect to how polypropylene responds to human tissue. I want to ask some questions based on your experience as a clinician what you have seen in terms of the healing process with patients who have had polypropylene implants, either in the form of sutures or in transvaginal mesh. Based upon your experience as a physician, how would you describe the tissue response in the body to polypropylene?		
rg121313, (Pages 462:13 to 463:8) 462 THE WITNESS: My clinical experience with polypropylene has been, again, I'm privileged that I've been able to operate in the era of using these Type I polypropylene mesh products, because I know that other implants, like Goretex and whatnot, were less well tolerated in years past. But I've just simply never had a material problem with polypropylene, period. And I tell patients that, you know, I've now done these in the thousands when you talk about slings, for example, I have 463 literally never seen an infection or rejection, some kind of a delayed strange material complication, inflammation, ever, not once. Complications, of course, are	BSC has previously designated this testimony. Plaintiffs adopt and incorporate any objections as set forth in their counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

5 inherent to anything we do. But on a material 6 level, absolutely no concerns recommending it 7 to my patients, to my wife, to my mother, 8 clinically based on what I know as a surgeon.		
rg121313, (Pages 463:15 to 464:11) 463 15 Q. But have you ever seen any 16 evidence, clinical evidence, of mesh shrinkage, 17 for example? 18 A. I truly have not. I know that 19 that's been a point of discussion, and I have 20 my -- I think that, you know, I have my clinical 21 clinical experience to indicate that I've just 22 never seen that happen. 23 I think there's certainly a 24 fibrous scar that forms around any surgery. 464 1 That's the nature of surgical scar even 2 probably with native tissue. 3 So if there's any contraction or 4 scar deposition, that may be plausible as a 5 reason why things can contract slightly. But 6 I've just never seen that clinically with this 7 technique. 8 Q. What about degradation or 9 degrading of the mesh, have you ever seen that 10 clinically? 11 A. No.	BSC has previously designated this testimony. Plaintiffs adopt and incorporate any objections as set forth in their counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.
rg121313, (Pages 473:15 to 476:4) 473 15 As a clinician, do you believe 16 polypropylene mesh is a safe and appropriate 17 material for use in the treatment of prolapse? 18 A. Yes. 19 Q. As a clinician, do you believe the 20 Uphold is a safe and effective device for the 21 use in treatment of prolapse? 22 A. Yes. 23 Q. Is mesh appropriate for every 24 woman who's experiencing prolapse? 474 1 A. No. 2 Q. What kind of things weigh into 3 your risk/benefit equation in determining 4 whether or not a patient is an appropriate 5 candidate for the Uphold? 6 A. Well, we go through this every 7 day. It's a large part of our job is to talk	BSC has previously designated this testimony. Plaintiffs adopt and incorporate any objections as set forth in their counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

to the patient.
First of all, what's the severity of her prolapse. Is it a high grade prolapse in a woman prone to recurrence? Is it a recurrent case, she's already failed a native tissue repair. These are two factors that could steer you towards something more durable, whether it's transvaginal mesh or perhaps in some surgeons' hands an abdominal colpopexy, we reach for these next level operations because we want to offer this woman with severe prolapse as one of her options a more durable repair. No question in my mind that these fill that role.
And then finally patient choice. I ask my patients directly every day what is your biggest goal and what is your biggest

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fear. And if you are unwilling to accept the risks and benefits of any potential procedure, it's not for you. For someone then that means native tissue repair is unacceptable because they will not accept a 30 percent risk of it bulging back in the future. And for other women they prefer the native tissue repair because they're not willing to accept the 3 or 2 or 5 percent risk of a mesh exposure, whatever it may be for her surgeon. And that's fair.
So it's about individual choice, it's about honest counseling, and that's how I select.
Q. Today what are the sources of information for physicians about the risks and benefits of the Uphold or similar products using transvaginal mesh?
A. Well, it's pervasive. I mean on the level of literature, you know, society, guideline statements, opinion papers, continuing medical education. Industry is a slice of that pie but actually a very small slice.

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The doctor who chooses to adopt this into his or her practice, you know, really has all tiers to get that sort of training or

4 expertise.		

1. **Objections to Counter Exhibits.**

   a. Goldberg 786, 827, 828, 829, 830, 831, and 832 have been previously designated by BSC. Plaintiffs adopt and incorporate the objections to these exhibits as set forth in Plaintiffs Objections and Counter-Designations to Roger Goldberg, MD, if any.

2. **Counter Exhibits to Counter Exhibits**

   a. Plaintiffs adopt and incorporate the exhibits designated in their counter exhibits for this witness.

DATED: July 20, 2015

Respectfully Submitted,

TRACEY & FOX LAW FIRM

/s/ Sean Tracey
Sean Patrick Tracey
State Bar No. 20176500
Shawn P. Fox
State Bar No. 24040926
Clint Casperson
State Bar No. 24075561
440 Louisiana, Suite 1901
Houston, TX 77002
(800) 925-7216
(866) 709-2333
stracey@traceylawfirm.com
sfox@traceylawfirm.com
ccasperson@traceylawfirm.com

/s/ *John R. Fabry*
John R. Fabry
Texas Bar No. 06768480
Mark R. Mueller
Texas Bar No. 14623500
MUELLER LAW, PLLC
404 West 7th Street
Austin, TX 78701
(512) 478-1236
(512) 478-1473 (Facsimile)
John.Fabry@muellerlaw.com
Mark@muellerlaw.com
Meshservice@muellerlaw.com

CERTIFICATE OF SERVICE

I hereby certify that on July 20, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

TRACEY & FOX LAW FIRM

/s/ Sean Tracey
Sean Patrick Tracey
State Bar No. 2176500
Shawn P. Fox
Clint Casperson
State Bar No. 24075561
State Bar No. 24040926
440 Louisiana, Suite 1901
Houston, TX 77002
(800) 925-7216
(866) 709-2333
stracey@traceylawfirm.com
sfox@traceylawfirm.com
ccasperson@traceylawfirm.com

/s/ *John R. Fabry*
John R. Fabry
Texas Bar No. 06768480
Mark R. Mueller
Texas Bar No. 14623500
MUELLER LAW, PLLC
404 West 7th Street
Austin, TX 78701
(512) 478-1236
(512) 478-1473 (Facsimile)
John.Fabry@muellerlaw.com
Mark@muellerlaw.com
Meshservice@muellerlaw.com